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Press Office

Press release

Update on somatropin-containing medicines

Review of somatropin officially started

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has started a review of the safety of somatropin-containing medicines authorised centrally or by national procedures in the European Union (EU). The CHMP will look into all available data on somatropin to reassess the benefit-risk balance of these medicines.

While this review is ongoing, the CHMP confirms that there is no immediate concern. However, prescribers are reminded to strictly follow the indications and the approved doses. The maximum recommended dose of 50µg/kg weight/day for somatropin-containing medicines should not be exceeded.

Somatropin is a human growth hormone, manufactured using recombinant DNA technology. It is used to treat a number of conditions associated with a lack of growth hormone and short stature. This includes children who fail to grow due to a lack of growth hormone, Turner syndrome or chronic renal insufficiency.

This review was initiated further to information received from the French medicines agency on a long-term epidemiological study in patients treated during childhood for idiopathic lack of growth hormone and idiopathic or gestational short stature with somatropin-containing medicines. The study results suggest an increased risk of mortality with somatropin therapy compared with the general population. This study on the safety and appropriateness of growth hormone treatments is funded by the European Commission and conducted by a European consortium of paediatric endocrinologists, epidemiologists and biostatisticians, involving eight EU countries. The study is still ongoing and further results are expected in the future.

Further updates on this review will be made as appropriate.



Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. A previous press release on the review of the safety of somatropin-containing medicines, dated 10 December 2010, is available on the Agency's website.
3. The reviews of the centrally authorised somatropin-containing medicines NutropinAq, Omnitrope and Valtropin are being conducted under Article 20 of Regulation (EC) No 726/2004. More information on these medicines can be found in the European public assessment reports (EPARs) available on the Agency's website.
4. The review of nationally authorised somatropin-containing medicines is being conducted under Article 107 of Directive 2001/83/EC. These medicines include Genotropin, Humatrope, Norditropin, Saizen and Zomacton.
5. The French safety study, 'Santé Adulte GH Enfant' (SAGhE), was initiated in October 2007 and aims at improving the knowledge on recombinant growth hormone and evaluating the health of young adults who have been treated during childhood with recombinant growth hormone. Using the national compulsory France-Hypophyse register, investigators of the SAGhE study identified more than 10,000 young adults who started a recombinant growth hormone treatment between 1985 and 1996. The available analysis covers approximately 7,000 of these patients. A report on the study has been submitted for publication to a scientific journal.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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